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10/751,292	01/02/2004	Mark A. Hoffman	CRNC.107055	1596

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EXAMINER	
MILLER, MARINA I	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,292	HOFFMAN ET AL.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' submission filed on 3/29/2006 is acknowledged. Claims 1-31 are pending. Claims 1-31 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

Claim Rejections - 35 USC § 101

Non-Statutory Subject Matter

The rejection of claim 1-31 under 35 U.S.C. 101 as being directed to non-statutory subject matter is withdrawn because applicants amended the claims and successfully argued that the claimed method produces a useful, concrete and tangible result.

Lack of Utility

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-31 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 1-31 were previously rejected for lack of patentable utility. Applicants argue that a method for providing inferred genetic findings to a user has an immediate benefit to the public by allowing a clinician to utilize the inferred genetic findings for medical treatment. Applicants point to paragraphs [0045], [0064], [0065], and [0072] for support. Applicants' arguments have been considered, but are found not persuasive.

In response to the arguments, it is noted that the asserted "utility," *i.e.*, allowing a clinician to utilize the inferred genetic findings for medical treatment, is not consonant with what is claimed. Specifically, in order for the result of the method (*i.e.*, providing inferred genetic findings) to be used for medical treatment of a person, one ordinarily skilled in the art must be aware of some correlation between a condition, trait, disease, and/or state of a patient and inferred genetic findings. Thus, although, the disclosed utility may be substantial, absent any disclosure about, for example, the connection of the "inferred" genetic findings to a particular disease or trait, the asserted utility is not specific.

Thus, for the reasons stated above and in the previous office action, the examiner maintains that claims 1-31 lack specific, substantial and credible utility, therefore the rejection is maintained.

Claim Rejections - 35 USC § 112

Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentations is "undue." These factors include, but are not limited to:

a) The breadth of the claims;
b) The nature of the invention;
c) The state of the prior art;
d) The level of one of ordinary skill;
e) The level of predictability in the art;
f) The amount of direction provided by the inventor;
g) The existing of working examples; and
h) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. 858 F.2d at 740. While all of these factors are considered, sufficient amount for a prima facie case are discussed below.

a) The claims are broad because they are drawn to a method for providing inferred genetic findings for a person comprising receiving a request, determining if the person has actual genetic findings, and if not, providing inferred genetic information, wherein the method does not recite an active, positive step of inferring (*i.e.*, without actually "inferring" anything). The instant specification does not provide specific guidance to practice the invention because it does not disclose how to get from actual genetic findings to the inferred result which is sent to a user without actually performing "inferring" and knowing how to infer (*i.e.*, parameters of "inferring" and a source from which genetic findings are "inferred" are not known).

b) The invention is drawn to a method for providing inferred genetic findings for a person.

c) Prior art analysis shows that providing "inferred" genetic findings actually requires a step of "inferring" by using a specific criterion, model, or/and algorithm and teaches that a source from which genetic findings are "inferred" must be known. For example, Grin, US 2003/0113727, discloses that if there is no history of a particular illness for an individual in a database, inferred genetic findings for the person are provided to a user wherein genetic findings are "inferred" by using an algorithm for identifying a possible risk of specific illness for a particular individual ([0030]-[0031], [0077]-[0081], and claim 11). The instant claims do not recite an active step of "inferring" nor any particular parameters/criteria for inferring.

The prior art of Harris, Computer Methods and Programs in Biomedicine, 32:37-44 (1990), teaches calculating a risk of specific genetic disorder (*i.e.*, inferred genetic findings) for genetic counseling based on family history using statistical algorithms (*e.g.*, Pearl's algorithm, a belief network, and clustering). Again, the instant claims do not recite an actual "inferring" nor parameters/criteria of inferring.

The prior art of Thomas, US 2004/0015337, teaches a Disease Information System that provides information which aids in the diagnosis and treatment of diseases to clinicians [0023]-[0026]. Thomas discloses computing and delivering a list of potential diagnoses and treatments, wherein information is derived from a variety of sources, *e.g.*, blood, saliva, urine, x-rays, MRI, can scan, biopsy, *etc.* Thomas also discloses inputting specific data collected from a patient (*e.g.*, pulse rate, sore throat, blood pressure), comparing the input data to a database by a computer, and outputting a possible treatment/diagnosis (*i.e.* inferred results are those based on the

comparison step) [0058]-[0063]. The instant claims do not recite any step of comparison, diagnosis or other "inferring," nor parameters/criteria of inferring, nor a source from which genetic findings are "inferred."

The prior art of Pickar, US 2003/0108938, teaches a method and a system for clinical trials for linking genomic and proteomic information to a clinical trial (abstract, claims 1 and 17). Pickar discloses inputting selected genetic information for patients suitable for a specific clinical trial and using a statistical analysis to analyze genetic data (wherein the results of the analysis are the "inferred" data) ([0062]-[0064] and example 1). Again, the instant claims do not recite a step of analyzing data or any other step of "inferring," parameters/criteria of inferring, nor a source from which genetic findings are "inferred."

d) The skill of those in the art of molecular biology and bioinformatics is high.

f) The specification does not provide any working examples and does not teach how to make and use the method without actually conducting a step of "inferring." In fact, the specification does not actually disclose how to "infer."

h) In order to practice the claimed invention, one skilled in the art must randomly select genetic findings and must guess which parameter and a source genetic material to use for "inferring." This constitutes undue experimentation.

Due to the undue experimentation required to obtain the goal of the invention, the lack of directions presented in the specification, the complex nature of the invention, and the state of the prior art showing that providing "inferred" genetic findings to a user actually requires conducting a step of analysis, comparison or other active step to produce "inferred" data by using a specific criterion, model, or/and algorithm and teaches that a source from which genetic findings are

"inferred" must be known, the specification fails to teach one skilled in the art how to use the claimed method for generating diagnostic or therapeutic output.

Second Paragraph

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 17, and 19 recite "actual" genetic findings. The instant claims were rejected in the previous office action because it was not clear whether an "actual" finding is intended to represent the fact of the presence of any genetic information for a patient in a database OR the presence of information indicating that the patient has, for example, a mutated (compared to normal) allele, gene, *etc.* Applicants argue that "actual genetic findings" represent the presence of any genetic information indicative that the person has a mutated gene.

In response, it is noted that the specification does not define the phrase "actual genetic findings" anywhere. However, the disclosure of paragraph [0033] is interpreted to be a description of "actual" genetic findings. Specifically, paragraph [0033] discloses that "the system may be queried to determine whether the patient has any genetic findings for a particular gene [*e.g.*, the presence of any genetic information for a patient for a gene in a database] .... The system may also be queried to find a specific genetic finding (e.g., a particular mutation in a specific gene)." Thus, the specification is interpreted to provide support that "actual" genetic findings represent the fact of the presence of information in a database OR the presence of information indicating that the patient has a mutated gene. Thus, for the reasons stated above and

in the previous office action, the examiner maintains that claims 1, 17, and 19 are indefinite, and the rejection is also maintained.

Claims 1 and 17 recite the limitation "if the person does not have actual genetic information, automatically providing inferred genetic information." The instant claims were rejected in the previous office action because it was not clear whether "providing inferred genetic findings" is intended to be an active, positive method step. Applicants did not address the rejection. The examiner maintains that the limitation is unclear, and therefore also maintains the rejection.

Claim 3 recites "a decision support rule." The instant claims were rejected in the previous office action because the limitation was not clearly defined. Applicants argue that "decision support rules" are described in paragraph [0030].

In response to the argument, it is noted that paragraph [0030] does not define "a decision support rule." Further, the specification does not exemplify a "decision rule" such that one skilled in the art would know what applicant intends by a "decision support rule." The specification only discloses that a computerized physician ordered application may have embedded logic to evaluate an electronic order [0030]. The prior art discloses initiating a request by a query protocol wherein a user selects, for example, specific parameters and a program or algorithm for classifying data (*e.g.*, a risk of genetic disease for a patient) (*see*, for example, Girn, US 2003/0113727 [0079]-[0081]; Pickar, US 2003/0108938 [0062]-[0063]; Morand, US 2002/0046054, [0049]). Although the prior art query protocol used for classifying data may be

interpreted as a "decision rule," the prior art does not teach clearly and unambiguously a "decision support rule" such that one skilled in the art would know what such a rule is. Therefore, one of ordinary skill in the art would not know whether a prior art rule or some other rule is intended by applicants. Thus, the examiner maintains that the limitation "a decision support rule" is indefinite, and therefore also maintains the rejection.

Claims 4, 15, 20, and 30 recite the limitation " the traversal pattern." The instant claims were rejected in the previous office action because there was insufficient antecedent basis for this limitation in the claims and the limitation was not clear. Applicants stated that the claims were appropriately amended and requested withdrawal of the rejection.

In response, it is noted that there is still insufficient antecedent basis for this limitation. The claims depend from claims 1, 12, 17, and 28, respectively, which do not recite a traversal pattern. Further, the limitation is not clear as neither the claims nor the specification defines a "traversal pattern." Thus, the examiner maintains that the limitation "the traversal pattern" is indefinite, and therefore also maintains the rejection.

Claim Rejections - 35 USC § 102

Claims 1-11, 14, and 17-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Girn, US 2003/013727.

The instant claims were previously rejected over Girn. Applicants argue that Girn does not teach determining first whether a person has actual genetic findings and if not, providing

inferred genetic findings for the person to a user. Applicants' arguments have been considered, but are found not persuasive.

In response to the arguments, it is noted that Girn teaches steps of receiving a request for genetic findings (*e.g.*, claim 11, [0030], [0077]) and determining if a person has actual genetic findings (*e.g.*, a family history regarding specific illnesses is collected and entered in a database, [0030]-[0031], [0077]-[0081], and claim 11). Girn further discloses a step of "if the person does not have actual genetic findings [*e.g.*, there is no history of a particular illness for an individual in a database], providing inferred genetic findings for the person to a use [*e.g.*, using an algorithm, identifying a possible risk of specific illness for a particular individual, [0030]-[0031], [0077]-[0081], and claim 11]." Girn also discloses providing inferred data to an individual and/or provider [0028] (*i.e.*, a user). Thus, Girn does disclose determining first whether a person has actual genetic findings and if not, providing inferred genetic findings for the person to a user. For the reasons stated above and in the previous office action, the examiner maintains that Girn anticipates claims 1-11, 14, and 17-27, and therefore the rejection is also maintained.

Claim Rejections - 35 USC § 103

Claims 12-13, 15-16, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girn, US 2003/013727, as applied to claims 1-11, 14, and 17-27 above, and further in view of Pikar, US 2003/0108938.

The claims were previously rejected over Girn and Pikar. Applicants argue that neither Girn nor Pikar teaches determining first whether a person has actual genetic findings and if not, providing inferred genetic findings for the person to a user. Applicants' arguments have been considered, but are found not persuasive.

The rejection is made under 35 U.S.C. 103(a) over a combination of references. The argument that Pikar does not teach determining first whether a person has actual genetic findings and if not, providing inferred genetic findings for the person to a user, is not persuasive as the examiner maintains that Girn does teach the limitation, as set forth in the previous office action and maintained above.

Applicant is reminded that under 35 U.S.C. 103(a), neither reference must necessarily teach "each and every" limitation, but a combination of references may make the claimed limitations obvious. Motivation to combine the teachings was provided in the previous office action mailed 12/27/2005, and is reiterated below:

"It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Girn to use genetic marker information, such as taught by Pickard, where the motivation would have been to monitor the composition of the population, as taught by Pickard [0062]."

Thus, for the reasons stated above and in the previous office action, the rejection is maintained.

Conclusion

No claims area allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller
Examiner
Art Unit 1631

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
5/17/06

MM